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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,068	09/20/2001	Hazire Oya Alpar	41577/263898	6302

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,068

Applicant(s)

ALPAR ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,6-10,12,13 and 26-33 is/are pending in the application.
4a) Of the above claim(s) 26-28 and 30-32 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,4,6-10,12,13,29 and 33 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed August 8, 2005 has been entered. The amendment filed August 8, 2005 has been entered. Claims 1, 7-8, 10 and 13 have been amended. Claims 2-3, 5, 11 and 14-25 have been cancelled. Claims 26-28 and 30-32 have been withdrawn from consideration. Claims 1, 4, 6-10, 12-13, 29 and 33 drawn only to positively charged cationic block copolymers or positively charged cationic surfactants are under consideration in this office action.

Withdrawal of Objections and Rejections

2. The following objections and rejections have been withdrawn:
- a) The rejection of claims 1, 3-4, 6-9, 12 and 29 under 35 U.S.C. 102(a) as being anticipated by Griffin et al., (1998);
 - b) The rejection of claims 1, 3-4, 6-10, 12-13 and 29 under 35 U.S.C. 102(e) as being anticipated by Park et al., (US Patent 6,267,987 Published July 31, 2001 with an earlier filing date of December 11, 1998);
 - c) The objection of claim 3 under 37 CFR 1.75(c); and
 - d) The rejection of claims 1, 3-4, 6-10, 12-13 and 29 under 35 U.S.C. 112, second paragraph.

Response to Arguments

3. Applicant's arguments filed August 8, 2005 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of claims 1, 4, 6-9, 12-13, 29 and 33 under 35 U.S.C. 102(b) as being anticipated by Duncan et al., (WO 94/20070 published September 15, 1994) is maintained for reasons already of record. The rejection was on the grounds that Duncan et al., taught a vaccine composition comprising pharmaceutically acceptable particles selected from polymeric microcapsules wherein the particles comprise a biologically active agent that generates a protective immune response in an animal to which it is administered; in combination with an adjuvant chemical which increases the effect of the biologically active agent by acting as an immunostimulant, said adjuvant chemical being a positively charged cationic block copolymer and a positively charged cationic surfactant.

Applicants' assert that Duncan et al., teach a broad class of polycations and that there is no reason why a skilled person in the art would alight on the particular form of polycation. However, Duncan et al., teach compositions

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comprising an adjuvant chemical having adjuvant properties wherein the adjuvants include PluronicTM block copolymers at pages 9-10, para. 1. Moreover, Duncan et al., teach that the antigens are more immunogenic when they are incorporated into the polymeric microparticles (page 2, para.4). Therefore, Duncan et al., does more than point to a broad class of divergent compounds as applicants state. Duncan et al., clearly and with particularity points to specific positively charged cationic block copolymers. Therefore applicants' argument is not persuasive.

Applicants' assert that Duncan et al., fail to disclose the use of adjuvants having dual function of being an immunostimulant and a functional component of the microcapsule wall. However in response to applicant's argument, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Moreover, the claim does not include any additional components which the prior art does not have. Finally, applicant is reminded that the claims are to a composition and not to a method use, therefore the additional uses or the dual functions of the adjuvants are irrelevant, since the prior art structure is capable of performing the intended use.

Applicants' assert that certain block copolymers are all purpose carriers and that no adjuvant or immunostimulant properties are disclosed in the reference. However, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but

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only that the subject matter is in fact inherent in the prior art reference. See also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) which state "[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention." Therefore, the immunostimulant properties which applicants' refer to are an inherent property of the positively charged cationic block copolymer and positively charged cationic surfactants. Therefore, Duncan et al., is not required to teach the inherent immunostimulant properties of the copolymers to meet the limitations of the claims. Rather the requirement is that Duncan et al., disclose those copolymers, which Duncan et al., does. Therefore, the block copolymers of Duncan et al., meet the instantly claimed limitations and applicants' assertions are irrelevant. Therefore applicants' argument is not persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

5. The written description rejection of claims 1, 4, 6-10, 12-13, 29 and 33 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons already of record.

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The rejection was on the grounds that the claims are so broad that they encompass every type of vaccine and biologically active agent which effects all types of diseases, disorders and infections in any type of animal.

Applicants argue that their invention is drawn to a composition that when utilized with known vaccines of known effect and administered non-parenterally, would facilitate induction of comparable levels of systemic immunity to that elicited by conventional sub-cutaneous and intra-muscular injection. However the claims are drawn to a vaccine composition comprising pharmaceutically acceptable particles wherein the particles comprised a biologically active agent in combination with an adjuvant chemical. The generic statements drawn to the vaccine composition and biologically active agent do not provide ample written description for the compounds since the claims do not describe a single structural feature associated with the biologically active agent. Therefore applicants assertion that the invention is drawn to a composition that when utilized with known vaccines of known effect and administered non-parenterally, would facilitate induction of comparable levels of systemic immunity to that elicited by conventional sub-cutaneous and intra-muscular injection is not persuasive since the instantly described vaccine compositions do not teach a composition utilized with known vaccines of known effects. Moreover, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic, yet these examples are not disclosed by the specification. It is unquestionable claim 1 is a broad generic with respect all possible compounds encompassed by the claims. The possible structural variations are

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limitless. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite functional characteristics such as the biologically active agent generating a protective immune response, the increased effect of the biologically active agent acting as an immunostimulant and how the polymeric microcapsules are obtained. However the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives.

As previously pointed out there is merely a general outline of vaccines that do not apply directly to the instant invention. Moreover, the specification discloses that immune responses, i.e., elevated antibody levels, were generated in mice, however it is well known that merely generating an immune response does not equate to providing protective immunity. Thus the specification fails to provide an adequate written description of a vaccine comprising an undisclosed biologically active agent and adjuvant that will provide protective immunity to all types of infections and diseases. This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose of preventing any type infection or disease. Without this demonstration, the skilled

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artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced. The specification fails to teach the identity a vaccine with the claimed characteristics. Furthermore, the specification fails to adequately disclose a description of the claimed vaccines, thus a skilled artisan would be required to *de novo* locate, identify and characterize the claimed vaccines and biologically active agent with the recited abilities.

Therefore applicants' arguments are not persuasive and the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph, thus the rejection is maintained.

New Matter

6. The new matter rejection of claims 1, 4, 6-10, 12-13, 29 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons of record. The rejection is on the grounds that a vaccine composition comprising pharmaceutically acceptable particles selected from polymeric microcapsules or liposomes, the particles comprising a biologically active agent that generates a protective immune response in an animal to which it is administered', in combination with an adjuvant chemical which increases the effect of the biologically active agent by acting as an immunostimulant, said adjuvant chemical being selected from the group consisting of: A) polyornithine, B) a member selected from the group consisting of water soluble vitamins and water soluble vitamin derivatives,

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C) a member selected from the group consisting of positively charged cationic block copolymers and positively charged cationic surfactant; D) a clathrate, E) a complexing agent, F) cetrimides, G) a S-layer protein, H) Methyl-glucamine; subject to the following provisos a) when the adjuvant chemical is administration to a mucosal surface, and selected from A, the composition is for b) when the particles are polymeric microcapsules, they are either obtainable using a double emulsion solvent evaporation method or have an adjuvant chemical incorporated at the surface.

Neither the specification nor originally presented claims provide support for a vaccine composition comprising a member selected from the group consisting of water soluble vitamins and water soluble vitamin derivatives, or a member selected from the group consisting of positively charged cationic block copolymers and positively charged cationic surfactant when the particles are polymeric microcapsules, they are either obtainable using a double emulsion solvent evaporation method or have an adjuvant chemical incorporated at the surface.

Applicants' did not point to support in the specification for the vaccine composition. Page 6, lines 4-9 provide support for the use of either positively charged block copolymers or positively charged cationic surfactants, not both. There is no support for a member selected from the group consisting of water soluble vitamins and water soluble vitamin derivatives, as now claimed.

Applicants failed to point to support drawn to teaching generic vaccine composition which can treat all infections and diseases. Thus, it appears that the

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entire specification appears to fail to recite support for the newly recited vaccine composition with the ability to provide protective immunity to any and/or all infections and/or diseases. Therefore, applicants' must specifically point to page and line number support for a vaccine composition comprising pharmaceutically acceptable particles selected from polymeric microcapsules or liposomes, the particles comprising a biologically active agent that generates a protective immune response in an animal to which it is administered', in combination with an adjuvant chemical which increases the effect of the biologically active agent by acting as an immunostimulant, said adjuvant chemical being selected from the group consisting of: A) polyornithine, B) a member selected from the group consisting of water soluble vitamins and water soluble vitamin derivatives, C) a member selected from the group consisting of positively charged cationic block copolymers and positively charged cationic surfactant:, D) a clathrate, E) a complexing agent, F) cetrimides, G) a S-layer protein, H) Methyl-glucamine; subject to the following provisos a) when the adjuvant chemical is administration to a mucosal surface, and selected from A, the composition is for b) when the particles are polymeric microcapsules, they are either obtainable using a double emulsion solvent evaporation method or have an adjuvant chemical incorporated at the surface as recited by the amended claims. Therefore, the claims incorporate new matter and the rejection is maintained.

New Grounds of Rejection***Claim Objections***

7. Claims 12 and 33 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 12 and 33 are drawn to the composition being administered to a mucosal surface or parenterally and the adjuvant being coated on the surface of the microcapsule, however neither the administration nor the surface coating further limit the composition. The administration and surface coating do not add more components to the composition, therefor the claims are objected to. Therefore the claims do not further limit the composition and appropriate clarification is required to overcome the objection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duncan et al., (WO 94/20070 published September 15, 1994) in view of Griffin et

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al., (1998). The claims are drawn to a vaccine composition further comprising microcapsules which comprise poly-(L-lactide). Duncan et al., has been previously discussed however Duncan et al., do not teach microcapsules comprising poly-(L-lactide).

As previously discussed and admitted by applicant, Griffin et al., clearly teach the microencapsulation of vaccine compositions comprising the V antigen with poly-(L-lactide).

Therefore, it would have been prima facie obvious at the time of applicants' invention to have used the known vaccine composition as taught by Duncan et al., and modify the compositions to include poly-(L-lactide) and adjuvant agents in a microparticle formulation as taught by Griffin et al. One would have a reasonable expectation of success in having a vaccine composition, a mucoadhesive which already has well known properties such as low cost, high biocompatible, being biodegradable, easy chemical modification, having gel-forming properties and being useful in microspheres systems and combining it with antigens and cationic pluronic adjuvants in particle formation to achieve enhanced mucosal absorption. Moreover, no more than routine skill would have been required to modify the well known composition since the modification merely incorporates using antigenic and adjuvant material within microparticulate polymeric carriers to enhance adsorption.

Conclusion

9. No claims are allowed.

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10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 

October 11, 2005


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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